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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,736	06/20/2005	Bandi Parthasaradhi Reddy	H1089/20025	8607

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EXAMINER

RAHMANI, NILOOFAR

ART UNIT PAPER NUMBER

1625

DATE MAILED: 06/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/539,736

Applicant(s)

PARTHASARADHI REDDY ET AL.

Examiner

Niloofer Rahmani

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3 and 29-65 is/are pending in the application.
- 4a) Of the above claim(s) 46-65 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 29-45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

1. Claims 1-3, and 29-65 are currently pending in the instant application.

Claims 4-28 are cancelled.

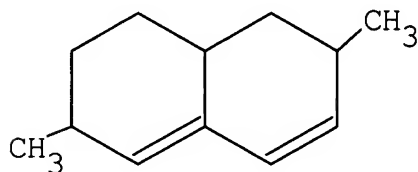
Applicant's election with traverse of group I in the reply filed on 04/28/2006 is acknowledged. The applicant's traverse is on a ground as followed:

1. The relationship among the subject matter defined by the amended claims is such that it involves one or more of the same or corresponding special technical features that make a contribution over the prior art.

The special technical feature as claimed is not taught by the prior art.

Applicant's argument is not persuasive for the following reasons:

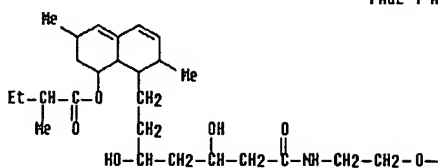
1. The common core is



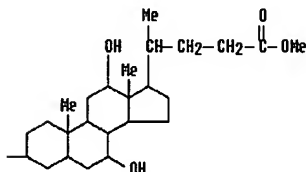
, because it is the only thing that does not change between group I-III. US 5,462,933 show the same special technical feature (columns 67-68, formula

Cholan-24-oic acid, 3-[2-[[7-[1,2,6,7,8,8a-hexahydro-2,6-dimethyl-8-(2-methyl-1-oxobutoxy)-1-naphthalenyl]-3,5-dihydroxy-1-oxoheptyl]amino]ethoxy]-7,12-dihydroxy-, methyl ester, [3.beta.[3R,5R,7[1S,2S,6R,8S(S),8aR]],5.beta.,7.alpha.,12.alpha.]

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),

which a common core is known. Therefore, it is not applicant's contribution to the art. In addition, applicant is allowed one process of making for the special technical feature and claim 1 has two processes.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-45 in part, which is drawn to a process for the preparation of simvastatin of formula I using a compound of formula II are examined. Claims 46-65 and 1-45 in part which is drawn to a process for the preparation of simvastatin of formula I using a compound of formula III remaining subject matter being drawn to the non-elected invention are withdrawn per 37 CFR 1.142(b).

This application contains claims 46-65 and 1-45 in part drawn to an invention nonelected with traverse in remark, filed on 04/28/2006. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b)

if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

**2. Priority**

This application is filed on 06/20/2005, which is a 371 of PCT/IN04/00003, filed on 01/02/2004.

**3. Claim Rejections - 35 USC § 112**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 is rejected because the term " 2" is confusing. Does claim 3 depend on claim 2? In claim 3, "2" does not appear to <sup>be</sup> strike out. Correction is required.

**4. Claim Rejections - 35 USC § 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

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(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-3, and 29 are rejected under 35 U.S.C. 102(a,e) as being anticipated by Sambasivam et al. US 6,603,022. 102(a) rejection is in light of publication date, which is 08/05/2003 of US 6,603,022, and 102(e) is in light of filing date, which is 07/12/2002 of US 6,603,022 vs. the effective filing date of the instant application, which is 01/02/2004. Sambasivam et al. disclosed the instant claimed process on columns 15-18, wherein R<sub>1</sub> and R<sub>2</sub> being heteroalkyl, heteroaryl, moiety or R<sub>1</sub> and R<sub>2</sub> being together heterocyclic moiety. Therefore, the instant claims are anticipated by Sambasivam et al.

**5. Claim Rejections - 35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-3, and 29-45 are rejected under 103(a) as being unpatentable over Sambasivam et al. US 6,603,022 and Kumar et al., US 5,763,646.

Determination of the scope and content of the prior art (MPEP §2141.01)

Sambasivam et al. on columns 15-18 disclosed analogous processes for obtaining Simvastatin using the same R<sub>1</sub> and R<sub>2</sub> substituents without hydroxyl protecting groups. Kumar et al. US 5,763,646 on columns 3-4 disclosed analogous processes for obtaining Simvastatin using different R<sub>1</sub> and R<sub>2</sub> as amid substituents with hydroxyl protecting groups.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant claims and the prior art process is that the Sambasivam et al. process does not include hydroxyl-protecting groups. Kumar et al. process has different R<sub>1</sub> and R<sub>2</sub> substituents.

Finding of prima facie obviousness-rational and motivation (MPEP §2142.2143)

One having ordinary skill in the art would be motivated to modify the process of Sambasivam et al. without hydroxyl protecting groups to the instant

process with the Kumar et al. process with the different  $R_1$  and  $R_2$  substituents. It is within skill in the ordinary artism.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Niloofar Rahmani whose telephone number is 571-272-4329. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas Mckenzie, can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NILOOFAR RAHMANI

06/21/2006

Nr



D. MARGARET SEAMAN

PRIMARY EXAMINER

GROUP 1625